Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/573,753	**Applicant(s)** CEBON ET AL.	
	Examiner MARIANNE DIBRINO	**Art Unit** 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *20-22,25,26 and 34-37*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

/Ram R. Shukla/
Supervisory Patent Examiner, Art Unit 1644

/DiBrino Marianne/
Examiner, Art Unit 1644

Continuation of 13. Other: Applicant's arguments have been fully considered but are not persuasive. With regard to the 102(b) rejection of record, the following applies. It is noted that the Inventors are authors along with others on the art reference cited. Applicant argues that the amount of ISCOM adjuvant is not taught by the art reference. However, Applicant is arguing a non-recited limitation, as the instant claims as amended, do not recite an amount of ISCOM adjuvant, nor any amount of any adjuvant, just "an amount of a composition containing full length NY-ESO-1 protein and a saponin based adjuvant, sufficient to induce an antibody response to NY-ESO-1 in said subject and reduce the risk of relapse." The art reference discloses that antibody titres greater than 1:100,000 were commonly seen, and also teaches the antibody titre versus dose levels of different doses (A,B,C & D) of NY-ESO-1 ISCOM ™. Figure 2 of the instant specification appears identical to the said art teaching at the first four panels of Figure 2 (i.e., for doses A,B,C & D). The instant specification discloses that out of 19 total patients given dose A, B or C, only 2/19 had relapsed after a median follow up of 748 days versus 5/7 patients receiving the placebo and 6/16 patients who received dose D (the NY-ESO-1 protein alone). The amounts of protein administered are the same in the art reference and the specification, and the antibody titres achieved are also the same. The specification shows that thse patients receiving dose A, B and C had a reduced risk of relapse. Therefore the method of the art reference appears to be the same as the process of the prior art absent a showing of differences. With regard to Applicant's arguments about unexpected results, the art reference shows the same result, so the result is not unexpected, and in addition, the claims do not recite that the risk of relpase is reduced for the length of time that Applicant asserts is unexpected. With regard to Applicant's arguments pertaining to the 103(a) rejection of record based upon WO 98/14464, Batchu and WO 03/076455, Batchu teaches that NY-ESO-1 based therapies can be used for treatment or to reduce the relapse inpatients by eradicating residual tumor cells, even though Batchu did not exemplify the teaching. The primary reference teaches use of NY-ESO-1 in a saponin based adjuvant for treatment of cancer and WO 03/076455 teaches that ISCOM and ISCOMATRIX are useful saponon-based adjuvants. It would have been prima facie obvious to have combined the references to reduce risk of relapse similarly to treatment, in order to produced the claimed invention with a reasonable expectation of success as enunciated in the instant rejection. With regard to the 103(a) rejection of record based upon these three references and further in view of Jager and '386, Applicant's arguments about Jager are not persuasive. Batchu et al teach that CD8+ T cell responses can be produced to help reduce the risk of relapse by eradicating residual tumor cells. Jager et al teach peptides that can induce CD8+ T cell responses to the NY-ESO-1 protein. Therefore, Jager does not have to provide indication that the peptides are useful to prevent relapse. Jager is being argued separately by Applicant, as is the '386 reference. With regard to Applicant's arguments about the 103(a) rejection of record based upon Cebon as the primary reference, the Examiner's response to Applicant's arguments above apply hereto, as do the Examiner's response to Applicant's argument about unexpected results. The instant rejection is maintained for these reasons and for the reasons of record.

A request under 37 CFR 1.105 is attached hereto.